Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Randomized clinical trial of comparing oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children

Protocol summary

Summary

(1) Objectives: Our aim in this is to compare effects of oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children. (2) Design: This a randomized not blinded clinical trail. Study population are 60 children between 5 to 14 years old referring to Children Hospital emergency with mild to moderate asthma attack. These children will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent. For randomizing the patients we will use Excel software (computerized randomization). (3) Setting and conduct: Patients will be randomly divided into two groups of receiving Salbutamol spray plus oral prednisolon and receiving Salbutamol spray plus Budesonide spray. Patients will be visited in first (acute attack), third and seventh day (end of treatment) of treatment and clinical examination, respirometry and pixelometry will be performed. Severity of asthma will be defined in all the visits. Inclusion criteria are having mild to moderate asthma attack and age between 5 to 14 years old. Exclusion criteria are unwillingness to participate in the study. (4) Intervention: First group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus oral prednisolon (2 milligrams per each kilograms of body weight for one week). Second group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus Budesonide spray (2 puffs every 12 hours, for one week, each puff contains 200 milligrams of the drug). (5) Main outcome measures: Spirometry (FEV1, FEV1/FVC, FEF %25-%75) and pixelometry criteria will be evaluated on first and seventh day and diurnal and nocturnal symptoms will be evaluated on first, third and seventh day of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101214988N1**
Registration date: **2013-11-05, 1392/08/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-05, 1392/08/14

Registrant information

Name

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Name of organization / entity

Pediatric Health Research Center,Tabriz University of Medical Sciences

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+98 41 3526 2265

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2014-01-10, 1392/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of comparing oral and inhalant corticosteroids in treatment of mild to moderate attack of asthma in children

Public title
Comparison of two kind of drugs in the treatment of asthma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Having mild to moderate asthma attack; Age between 5 to 14 years old. Exclusion criteria: Unwillingness to participate in the study.
Age
From **5 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Ethics committee، Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz
City
Tabriz
Postal code
Approval date
2013-06-08, 1392/03/18
Ethics committee reference number
5/4/2240

Health conditions studied

1

Description of health condition studied
Asthma
ICD-10 code
J45
ICD-10 code description
Asthma

Primary outcomes

1

Description
Forced expiratory volume in the first second
Timepoint
In the first and seventh day of the study
Method of measurement
By using spirometry device

2

Description
FEV1/FVC
Timepoint
In the first and seventh day of the study
Method of measurement
By using spirometry device

3

Description
Diurnal symptoms of the disease
Timepoint
In the first, third and seventh day of the study
Method of measurement
By examiner

4

Description
Nocturnal symptoms of the disease
Timepoint
In the first, third and seventh day of the study
Method of measurement
By examiner

Secondary outcomes

empty

Intervention groups

1

Description
First group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus oral prednisolon (2 milligrams per each kilograms of body weight for one week).
Category
Treatment - Drugs

2

Description
Second group will be treated with Salbutamol spray (2 puffs every four hours for 48 hours, each puff contains 100 micro grams of the drug) plus Budesonide spray (2 puffs every 12 hours, for one week, each puff contains 200 milligrams of the drug)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children Hospital
Full name of responsible person
Dr. Masoumeh Ghasempour
Street address
Tabriz Children Hospital, Sheshgelan Street, Farmanfarmayan Street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Seyyed Kazem Shakouri
Street address
Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah square, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz Children Hospital
Full name of responsible person
Dr. Masoumeh Ghasempour
Position
Pediatric diseases resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr. Nemat Bilan
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Professor of pediatric lung diseases
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz Children Hospital
Full name of responsible person
Dr. Masoumeh Ghasempour
Position
Pediatric diseases resident
Other areas of specialty/work
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Department of Pediatric diseases, Tabriz Children Hospital, Sheshgelan Street, Farmanfarmayan Street,

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty